UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	Consolidated No. 09-CV-11267 (GAO)

MEMORANDUM IN SUPPORT OF
INDIVIDUAL DEFENDANTS' MOTION TO DISMISS

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PRELIMINARY STATEMENT

Mark R. Bamforth, Alison Lawton, Geoffrey McDonough, David P. Meeker, Henri A. Termeer, and Michael S. Wyzga ("the Individual Defendants") join in Genzyme's motion and move separately to explain why, in addition to the reasons given there, the claims against the Individual Defendants should be dismissed. The Plaintiffs attempt to veil their standard fraud-by-hindsight claims in a blizzard of facts that the Individual Defendants supposedly "knew", but they do not allege any facts which give rise to a strong inference that their conclusory allegations were actually known by any of the Individual Defendants at the relevant times, that is, when the Individual Defendants were making the supposedly fraudulent statements. The most plausible and reasonable inference to be drawn from the facts alleged is that the Individual Defendants accurately reported the facts as they knew them and accurately stated their reasonable beliefs about Genzyme's future prospects.

The Complaint is defective as to the Individual Defendants in three ways. *First,* the Complaint asserts blanket liability for every allegedly false statement without allegations tying each Individual Defendant to each statement. Each Individual Defendant can be liable only for his or her own statements. The Complaint attempts to avoid pleading specifics by apparently invoking the group pleading doctrine, but that pleading presumption did not survive enactment of the Private Securities Litigation Reform Act of 1995, Pub. L. 104-67, 109 Stat. 737 ("the PSLRA") and does not substitute for allegations of each Individual Defendant's role in making the alleged misstatements. *Second,* the Plaintiffs have not satisfied the PSLRA's standard for pleading scienter with respect to any of the Individual Defendants. The Plaintiffs ask the Court to presume that the Individual Defendants, by virtue of their positions, must have known (or were reckless in not knowing) that what they were telling investors was false or misleading without alleging facts to support even a plausible inference, much less a cogent and compelling one, that

the Individual Defendants actually knew facts that contradicted their public statements. *Third,* the Plaintiffs make no plausible allegations that any one of the Individual Defendants, let alone all of them, had control over Genzyme and were culpable participants in any of Genzyme's alleged conduct, and thus the Complaint does not state a claim for control person liability under § 20(a) of the Exchange Act. For these reasons, the Court must dismiss the Complaint as against the Individual Defendants with prejudice.

ARGUMENT

A. The Complaint Fails To State A Claim Under § 10(b) and Rule 10b-5.

To allege a claim under § 10(b) and Rule 10b-5, the Plaintiffs must allege that each Individual Defendant made : (1) "a material misrepresentation (or omission)"; (2) with "scienter, i.e., a wrongful state of mind"; (3) in "connection with the purchase or sale of a security"; (4) on which the Plaintiffs relied (5); and on account of which the Plaintiffs suffered an "an economic loss" (6) caused by the material misrepresentation ("loss causation"). *See In re Stone & Webster, Inc. Secs. Litig.*, 414 F.3d 187, 193 (1st Cir. 2005). The Complaint fails to allege which material misrepresentations were made by each of the Individual Defendants (beyond oral statements specifically attributed to each and written statements signed by two of the Individual Defendants) or to plead facts sufficient to give rise to an inference of scienter that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.,* 551 U.S. 308, 314 (2007).

1. The Complaint Impermissibly Asserts that Each Individual Defendant is Liable for Every Allegedly Fraudulent Statement Without Pleading Each Individual's Role in Making Those Statements

The Plaintiffs allege that each Individual Defendant is liable for every false statement alleged. This is classic group pleading. While the Complaint does identify the speakers of oral statements, it does not allege the role each Defendant played in Genzyme's written disclosures or

any role the Individual Defendants played in the oral statements of others. The claims against the Individual Defendants fail unless the Complaint alleges specific facts tying them to any alleged misstatement.

a. Group Pleading

i. Group Pleading Is Impermissible Under the PSLRA.

The so-called group pleading doctrine is a presumption, adopted by some circuits before the PSLRA, that certain corporate statements are the collective statement of the corporation's officers. *See, e.g., In re Cabletron Sys., Inc.,* 311 F.3d 11, 40 (1st Cir. 2002) (before the PSLRA, the First Circuit recognized a limited version of the doctrine).[1] The First Circuit has applied the doctrine to documents such as an annual report that contained allegedly fraudulent statements. *Serabian v. Amoskeag Bank Shares, Inc.,* 24 F.3d 357, 367-68 (1st Cir. 1994); *see also In re Raytheon Secs. Litig.,* 157 F.Supp.2d 131, 152 (D. Mass. 2001).[2]

Group pleading is impermissible under the PSLRA, and it is inconsistent with the Supreme Court's recent holdings in *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544 (2007), and *Ashcroft v. Iqbal,* 129 S.Ct. 1937 (2009). One of the purposes of the PSLRA is to curb the practice of naming "peripheral defendants" for the purposes of coercing a settlement from

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[1] The classic statement of the doctrine is:
In cases of corporate fraud where the false or misleading information is conveyed in prospectuses, registration statements, annual reports, press releases, or other "group-published information," it is reasonable to presume that these are the collective actions of the officers. Under such circumstances, a plaintiff fulfills the particularity requirement of Rule 9(b) by pleading the misrepresentations with particularity and where possible the roles of the individual defendants in the misrepresentation.
Wool v. Tandem Computers, Inc., 818 F.2d 1433, 1440 (9th Cir. 1987) (citations omitted).

[2] In *Raytheon,* which post-dates the PSLRA, the Court found, relying on district court opinions from other jurisdictions, but no appellate decisions, that the group pleading doctrine survived enactment of the statute. *Raytheon,* 157 F.Supp.2d at 152-53. But the court engaged in no analysis of the effect of the PSLRA on the doctrine, simply adopting what it took to be the majority view, while noting that "the minority view has its merits." *Id.* at 153. *Raytheon* is, of course, not a binding precedent here, and its lack of justification for its holding deprives it of persuasive value, especially in light of the text and policies of the PSLRA and the appellate decisions discussed below.

them—or more realistically, from their D&O insurers. *See* S. Rep. No. 104-98, at 20-21 (1995), *as reprinted in* 1995 U.S.C.C.A.N. 679, 699-700.

Appellate courts that have considered the question agree that the group pleading doctrine is inconsistent with the PSLRA and is no longer a substitute for pleading actual facts regarding each defendant's role. In *Southland Secs. Corp. v. Inspire Ins. Solutions, Inc.,* 365 F.3d 353, 364-65 (5th Cir. 2004), for example, the Fifth Circuit held that the PSLRA's requirement—plaintiffs must set forth the untrue statements with particularity as to "the defendant" and plead facts giving rise to a strong inference that "the defendant" acted with scienter—could only be read to require pleading of such facts with respect to *each* defendant. Thus, it concluded, group pleading is simply inconsistent with the statute. *Accord Winer Family Trust v. Queen,* 503 F.3d 319, 335-37 (3d Cir. 2007); *Makor Issues & Rights, Ltd. v. Tellabs,* 437 F.3d 588, 602-06 (7th Cir. 2006), *rev'd on other grounds,* 551 U.S. 308 (2007) [*Makor I*]. *But see, e.g., In re Oxford Health Plans, Inc.,* 187 F.R.D. 133, 142 (S.D.N.Y. 1999). The First Circuit has recognized that the PSLRA calls the doctrine into question, while leaving it open as a formal matter. *See Mississippi Pub. Employees Retirement Sys. v. Boston Sci. Corp.,* 523 F.3d 75, 93 n.10 (1st Cir. 2008); *Cabletron,* 311 F.3d at 40. As group pleading is inconsistent with the plain meaning and purpose of the PSLRA, the Court should not permit the Plaintiffs to avoid pleading their claim against each Individual Defendants by the expedient of lumping them all together.

ii. Even if it Survived the PSLRA, Group Pleading Does Not Apply To Oral Statements.

Even if the group pleading doctrine were viable today, it is a narrow exception to the ordinary rules of pleading. The doctrine cannot apply to oral misrepresentations made by an identifiable person. The group pleading doctrine has been applied to SEC filings, press releases or similar written statements that might be characterized as a "collective" statement of

management. *See, e.g., In re Allaire Corp. Secs. Litig.,* 224 F.Supp.2d 319, 340-41 (D. Mass. 2002); *In re Lernout & Hauspie Secs. Litig.,* 208 F.Supp.2d 74, 84-85 (D. Mass. 2002).[3] But neither this Court nor the First Circuit has ever applied the group pleading doctrine to oral misrepresentations, which by definition are not "group publications" but statements made by particular individuals. Courts elsewhere have squarely held that oral statements, just because they are statements by identifiable individuals, cannot support group pleading allegations. *See XOMA Corp. Secs. Litig.,* [1991-1992 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 96,491 at 92,161 (N.D. Cal. 1991); *Krieger v. Gast,* No. 4:99-CV-86, 2000 WL 288442, at *9 (W.D. Mich. Jan. 21, 2000); *see also Winters v. Stemberg,* 529 F.Supp.2d 237, 250 (D. Mass. 2008) (distinguishing "statements made by specific [defendants]" from statements in annual reports and other written documents; group pleading doctrine only applies to the latter). These cases are correctly decided, because in the case of an oral statement, there is no confusion about the author and no need to give the plaintiff the benefit of a presumption about the identity of the speaker.

2. The Complaint Fails to Alleged Facts Giving Rise to a Strong Inference of Scienter As to Each of the Individual Defendants

Under the PSLRA, the Complaint must plead with particularity facts giving rise to a strong inference of scienter:

> In any private action arising under this title in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this title, state with particularity facts giving rise to a strong inference that *the defendant* acted with the required state of mind.

Id. § 21D (b)(2), 15 U.S.C. § 78u-4(b)(2) (emphasis added). The statute requires the Plaintiffs to plead scienter with particularity as to each Individual Defendant.

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[3] Both of these cases rely on *Raytheon* and thus do not justify the group pleading doctrine adequately. See the discussion of *Raytheon* in footnote 2, *supra.*

In order to determine whether the facts pleaded with particularity give rise to a strong inference of scienter with respect to each Individual Defendant, the Court must consider both the Plaintiffs' proposed inferences and the defendants' proposed inferences to determine whether the inference of scienter the plaintiff wishes the Court to draw is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs,* 551 U.S. at 314. This must be done with respect to each Individual Defendant named in the Complaint. *See, e.g., Southland,* 365 F.3d at 364-65. As discussed in detail below, the Complaint entirely fails to allege specific facts from which the Court may infer that any of the Individual Defendants acted with fraudulent intent.

a. The Group Pleading Doctrine Does Not Permit Allegations of Collective Scienter

Even if it were permissible under the group pleading doctrine to attribute group published statements to the officers of a corporation who signed the statement, the doctrine only permits attribution of *statements* to members of a group. It does not permit attribution of states of mind to members of a group. The PSLRA requires allegations as to *each* defendant's scienter; it does not permit group allegations regarding state of mind. The statute provides that:

> the complaint shall, with respect to each act or omission alleged to violate this title, state with particularity facts giving rise to a strong inference that *the defendant* acted with the required state of mind.

Exchange Act, § 21D (b)(2) (emphasis supplied). Because the statute requires pleading of facts relating to "the defendant," even courts that continue to recognize group pleading have held that the PSLRA requires sufficient allegations of scienter with respect to *each* defendant:

> '[G]roup pleading' of scienter—as distinguished from collective authorship of a statement—runs afoul of the PSLRA's requirement that a plaintiff 'state with particularity facts giving rise to a strong inference that *the defendant* acted with the required state of mind.'

Pennsylvania Ave. Funds v. Inyx, Inc., No. 08 Civ. 6857(PKC), 2010 WL 743562, at *12 (S.D.N.Y. Mar. 1, 2010) (citation omitted) (emphasis in original); *see also, e.g., Winer,* 503 F.3d at 335; *In re Federal Nat'l Mortg. Ass'n Secs., Deriv. & ERISA Litig.,* 503 F.Supp.2d 25, 40 (D.D.C. 2007). Thus the question on this motion to dismiss is whether, *with respect to each of the Individual Defendants,* the Plaintiffs have pleaded facts that give rise to a strong inference of scienter. Collective scienter is not enough.

b. An Officer's Job Title Is Not Enough To Create a Strong Inference of Scienter

Under the PSLRA, it is improper simply to presume that executive officers, by virtue of their titles, have knowledge of the corporation's business operations as they relate to the allegations of the complaint. *See, e.g.*, *In re Ceridian Corp. Secs. Litig.,* 542 F.3d 240, 247 (8th Cir. 2008). *Latham v. Matthews,* 662 F.Supp.2d 441 (D.S.C. 2009), illustrates the point. There, the plaintiffs sued a medical device manufacturer and various officers, employees, and directors for securities fraud. The gist of the claim was that the defendants had touted the company's device to investors as ready to be marketed and producing sales, when in fact the product was never fully functioning and there were no sales. The court rejected the sufficiency of the allegations despite the plaintiffs' objection that "it would be absurd for the Individual Defendants, in their executive positions, not to know the truth about their core business operations."[4] The court noted that such a presumption was contrary to the PSLRA's heightened pleading standards. *Id.* at 467-68. Other courts have likewise rejected any presumption that

[4] The court did find the allegations sufficient with respect to two of the defendants. The first was a director who had made statements about sales to investors but who had later admitted to a confidential witness, quoted in the complaint, that his statements had been false. The second was a former CEO who was alleged to be "intimately involved" in the company's sales and marketing and who "admit[ted] as much."

officers must have scienter if the alleged misstatements involved core business operations. *See, e.g., Stevens v. Inphonic, Inc.*, 662 F.Supp.2d 105, 120-21 (D.D.C. 2009).

A plaintiff, in other words, must do more than assert that an executive, just because he or she is an executive, simply *must* have known what was going on in the corporation's business. The plaintiff must plead facts that give rise to a strong inference that the executive *actually did* know. Simply assuming that an officer, because he or she was an officer, had the relevant knowledge defeats the purpose of the PSLRA, namely, to avoid implicating defendants with no real connection to the alleged fraud in costly and time-consuming litigation.

c. An Officer's Sarbanes-Oxley Act Certification, Or His Signature On An SEC Submission, Is Not Enough To Create a Strong Inference of Scienter.

Many of the allegedly fraudulent statements in this case are contained in documents filed with the Securities and Exchange Commission—annual Form 10-Ks, quarterly Form 10-Qs, and current report Form 8-Ks. The Form 8-Ks require an authorized person's signature on behalf of Genzyme. The Form 10-Ks and 10-Qs require a registrant's principal executive officer and its principal financial officer to certify the accuracy of the Company's financial statements. *See* Sarbanes-Oxley Act of 2002, Pub. L. 107-204, § 302(a), 15 U.S.C. § 7241.[5] The statute also requires them to certify that "the periodic report containing the financial statements fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 … and that information contained in the periodic report fairly presents, in all material respects,

[5] The statute, in pertinent part, requires the chief executive officer and the chief financial officer to certify, in all annual and quarterly filings under §§ 13(a) and 15(d) of the Act, that
(1) the signing officer has reviewed the report;
(2) based on the officer's knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading;
(3) based on such officer's knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition and results of operations of the issuer as of, and for, the periods presented in the report …

the financial condition and results of operations of the issuer." *See id.* § 906, 18 U.S.C. § 1350. But it is well-established that making such a certification does not make an officer strictly liable for securities fraud on account of misstatements in annual or quarterly SEC filings:

> [I]f an allegation that a mandatory Sarbanes-Oxley certification was later proven to be inaccurate is sufficient to give rise to the requisite strong inference, scienter would be established in every case where there was an accounting error our auditing mistake by a publicly traded company, thereby eviscerating the pleading requirements for scienter set forth in the PSLRA.

Ceridian, 542 F.3d at 248 (quoting *Central Laborers' Pension Fund v. Integrated Elec. Servs. Inc.,* 497 F.3d 546, 555 (5th Cir. 2007)). The PSLRA has done away with whatever presumption may have existed before that a person's status can be a substitute for cogent and compelling allegations giving rise to a strong inference of scienter. The issue is whether the officer *actually had* a fraudulent or reckless state of mind, not whether his or her status within the company can substitute for proof of actual state of mind.

3. The Complaint Fails To State A Claim Under § 10(b) Against Any Of The Individual Defendants.

In light of the principles outlined above, the Complaint, despite its sheer length, fails to state a claim for securities fraud against any of the Individual Defendants. At bottom, the Complaint alleges nothing more than the Individual Defendants' inability to predict the future perfectly in clearly identified forward-looking statements.[6]

a. Henri Termeer

Henri Termeer is Genzyme's Chairman and Chief Executive Officer. That is the only non-conclusory fact that the Plaintiffs accurately plead about his alleged misstatements.

[6] Genzyme's brief fully addresses the affirmative disclosure obligations of Genzyme and the Individual Defendants.

i. Receipt of the Form 483s and the Warning Letter Is Insufficient To Give Rise To A Strong Inference Of Scienter.

The Complaint attempts to distinguish Mr. Termeer from the other Individual Defendants most clearly insofar as it alleges that he personally received Form 483s and a Warning Letter from the FDA. (Compl. ¶¶ 112, 184, 327). As Genzyme has shown in its brief, even a warning letter is merely "informal and advisory." *See In re Boston Sci. Corp. Secs. Litig.,* 490 F.Supp.2d 142, 160-61 & n.113 (D. Mass. 2007), *rev'd on other grounds sub nom. Mississippi Pub. Employees Retirement Sys. v. Boston Sci. Corp.,* 523 F.3d 75 (1st Cir. 2008). Because the communications from the FDA that Mr. Termeer received were not formal determinations that Genzyme was not complying with cGMPs or indications that the FDA would take enforcement action against Genzyme, they cannot support the allegation that Mr. Termeer actually knew, or was reckless in not knowing, that Genzyme was not in compliance with cGMPs. The most plausible inference from Mr. Termeer's response to the Form 483s, then, is that Mr. Termeer or others within Genzyme were addressing the FDA's points and did not in fact believe that the contents of the communications were material, or would affect Genzyme's prospects for approval of Lumizyme, or its future financial prospects.

ii. Termeer Was Not Personally Responsible For Ensuring Compliance With cGMPs.

The Complaint attempts to remedy its failure to plead adequately the existence of cGMPs violations at any relevant time by marrying Genzyme's later disclosures with a misstatement about the FDA's conclusions about Mr. Termeer's and other officers' roles in ensuring cGMPs compliance. The Complaint alleges that Mr. Termeer and "senior corporate management" had the personal primary responsibility for monitoring Genzyme's compliance with cGMPs. The Complaint otherwise lacks any allegation that Mr. Termeer or the other Individual Defendants were aware of any issues (whether they existed or not) on the factory floor.

The Plaintiffs base their assertion on a misreading of the FDA *Guide to Inspections of Quality Systems* (Compl. ¶ 44).[7] As they allege, the Guide does require FDA inspectors to evaluate "whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained." (Guide at 18).[8] But the Plaintiffs fail to point out that the Guide provides that a finding of a failure of management to ensure an adequate and effective quality system may be recorded on a Form 483, (Guide at 29-30) and neither of the two Form 483s that are central to this case, dated October 2008 and November 2009, made such a finding. There is nothing in the Guide, or elsewhere in FDA regulations, to permit an inference that Mr. Termeer or any of the Individual Defendants knew of any alleged cGMPs violations (if any existed) at the times they made the alleged misstatements.

iii. The Complaint Alleges No Communications To Termeer Or Other Facts That Could Plausibly Suggest He Had Scienter

As Genzyme has established in its brief, the Complaint does not plausibly allege that Genzyme was not in compliance with cGMPs at relevant times, how alleged manufacturing problems could affect Lumizyme approval or result in contamination, as the Plaintiffs have alleged, and even if it did, the Complaint contains *no allegations* about any meetings Mr. Termeer attended or memoranda, emails, or other communications he received that suggest that he knew of any alleged noncompliance with cGMPs. There are no allegations that Mr. Termeer had any knowledge that Genzyme's expectations for the approval of Lumizyme were misleading

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[7] A true copy of the *Guide* is attached as Exhibit 1 to the Declaration of Theodore J. Folkman, which is being filed with this memorandum. It is available at http://www.fda.gov/downloads/ICECI/Inspections/UCM142981.pdf.

[8] This Memorandum refers to the Guide as well as, later in this memorandum, transcripts of investor or analyst calls from which the plaintiffs have culled the allegedly fraudulent statements. It is proper, on a motion to dismiss, to refer to documents from which the complaint takes excerpts and to which it refers. *See Young v. LePone,* 305 F.3d 1, 10-11 (1st Cir. 2002) (reference to management letters referred to by and quoted in the complaint); *see also Hubbard v. BankAtlantic Bancorp, Inc.,* 625 F.Supp.2d 1267, 1279-80 (S.D. Fla. 2008) (investor conference call transcripts); *In re Wet Seal, Inc. Secs. Litig.,* 518 F.Supp.2d 1148, 1157-58 (C.D. Cal. 2007) (same).

because there was allegedly no chance Lumizyme would be approved. Indeed, there are no allegations that he received any information from which he could have concluded that his statements, or those made by his colleagues at Genzyme were not accurate. In short, there are no allegations at all, other than the allegations regarding receipt of Form 483s and the Warning Letter from the FDA (which are insufficient, as shown above and in Genzyme's brief) that Mr. Termeer had *any* knowledge that could be enough to infer scienter.

The Plaintiffs' only attempt to make this anything other than a pure fraud-by-hindsight case is their use of confidential sources within the company. Not one of these witnesses even suggests that Mr. Termeer (or anyone else allegedly involved in making statements on behalf of Genzyme) was aware of their allegations. (Compl. ¶¶ 63, 66, 78, 82).

iv. There Are No Allegations of Motive.

One would expect, given the long-running and high-risk scheme the Plaintiffs have alleged here, that there would be some plausible allegation of motive. This is particularly so in light of the disclosures about manufacturing problems Genzyme did make during the Class Period and the ready access shareholders and the public had to much of the information allegedly not disclosed. There is no allegation in this case of the kind of motive that often underlies allegations of securities fraud. There is no allegation that Mr. Termeer or any other Individual Defendant was making unusual sales of Genzyme stock. *Contrast Greebel v. FTP Software, Inc.,* 194 F.3d 185, 196-97 (1st Cir. 1999). There is no allegation that Mr. Termeer or Genzyme was contemplating any corporate transaction that could have been affected one way or the other by the alleged fraud. *Contrast, e.g., Goldstein v. MCI WorldCom,* 340 F.3d 238, 249-50 (5th Cir. 2003). Indeed, the Plaintiffs cite no motive at all.

The Plaintiffs allege, in a purely conclusory and insufficient way, that the Individual Defendants could not have believed that the Allston Landing facility could continue operating or

that Lumizyme would receive FDA approval: the Plaintiffs allege that the denial of approval of Lumizyme was "virtually inevitable" (Compl. ¶ 7, see also ¶ 55); the Individual Defendants "knew" that the problems were so severe that Genzyme would decide to abandon the goal of producing Lumizyme at the 2000L scale (Compl. ¶ 126), "knew" that their proposed corrective measures would be ineffective (Compl. ¶ 287), "knew" Genzyme had not addressed all of the FDA's concerns (Compl. ¶ 300), and "knew" that Genzyme had been overburdening the Allston plant. (Compl. ¶ 227). If all this is true, a delay in disclosure could serve no purpose because the truth would eventually come out, and Genzyme's performance would fail to meet the expectations announced by management.

It is far more reasonable to infer that the Mr. Termeer and his colleagues were doing precisely what they said they were doing—working to address the issues raised by the FDA in the Form 483s, and taking the steps necessary to gain approval of Lumizyme. *See In re Praecis Pharmas., Inc. Secs. Litig.,* No. 04-12581-GAO, 2007 WL 951695, at *12 (D. Mass. Mar. 28, 2007) (unreasonable to think that defendants "were more interested in fooling the stock market in the short term than succeeding in the product market in the long term"). Both ignoring the problems and misrepresenting them to the public could serve no purpose for Genzyme or its management.

v. The Inferences Of Proper Conduct Are Far More Plausible Than The Inferences Mr. Termeer Committed Fraud.

There are much more compelling inferences to draw than the Plaintiffs' preferred inference of fraud, particularly in light of the lack of any motive to withhold information or any explanation of why the Individual Defendants did what they are alleged to have done. The Court should infer from the fact that Mr. Termeer *did* disclose the viral contamination later that Mr. Termeer and the others disclosed material information when they knew it, and when it should

have been disclosed. Genzyme disclosed that it conducted investigations of the contamination at Geel and Allston Landing. (Compl. ¶ 139). There are no allegations that the investigations yielded results different from the results disclosed, and a premature announcement could *itself* have misled investors. *See N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc.,* 537 F.3d 35, 58 (1st Cir. 2001); *Higgenbotham v. Baxter Int'l, Inc.,* 495 F.3d 753, 758 (7th Cir. 2007).

Why would Mr. Termeer express optimism or positive expectations about the FDA's response to Genzyme's efforts to correct problems alleged by the FDA or the timetable for approval of Lumizyme (e.g., Compl. ¶¶ 217, 275)? The Plaintiffs want the Court to infer that in light of what actually happened—the FDA's concerns ultimately were not resolved, Lumizyme was not then approved—these statements must have been fraudulent. That is fraud by hindsight and nothing more. The inference that Mr. Termeer and others were accurately reporting what they had heard from the FDA is particularly strong in light of the lack of any intelligible motive to lie about these issues. It is also strong in light of Genzyme's frank admission, for example, that the FDA had not formally found conditions at the Allston plant to be satisfactory (Compl. ¶ 143). Mr. Termeer and the others lacked any control over the FDA, and if in fact they knew that conditions at the Allston facility were not satisfactory to the FDA, or that Lumizyme approval would indeed be held up by cGMPs issues, then they also must have known that investors would quickly learn of these problems when the FDA took action.

In short, given the absence of any allegations that Mr. Termeer had knowledge of facts that would lead him to believe that FDA approval of Lumizyme was imperiled, that there allegedly was a material problem with Genzyme's manufacturing practices, or that Genzyme had not responded appropriately and to the FDA's satisfaction to the FDA's concerns, the most

plausible inference is not that Mr. Termeer was attempting to hide from the market facts that would inevitably and shortly be revealed. The most plausible inference is that he believed the statements he was making about the prospects for Lumizyme's approval, Genzyme's finances, and the FDA's reaction to Genzyme's efforts to respond to the Warning Letter and Form 483s were true. In short, the Complaint does not sufficiently allege, in a non-conclusory way, that Mr. Termeer knew enough at the time he made his statements to permit the Court to conclude that he acted with an intent to deceive or defraud when making those allegedly false statements.

b. Michael Wyzga

According to the Complaint, Michael S. Wyzga was the chief financial and accounting officer and executive vice president for finance. (Compl. ¶ 27). With Mr. Termeer, he signed all relevant Form 10-Q and 10-K filings. (Id.).

The Complaint's failures with respect to Mr. Termeer are repeated for Mr. Wyzga, too. There are, however, two additional points to emphasize. First, leaving aside the Form 10-Ks and 10-Qs, which Mr. Wyzga, as CFO, signed, the Complaint alleges that Mr. Wyzga made only three statements (Compl. ¶¶ 238, 251, 268, 270), each of which had to do with financial matters. Mr. Wyzga is accused of giving growth-in-sales figures for Cerezyme, Fabrazyme, and Myozyme in July 2008. (Compl. ¶ 238). There is no allegation that his figures were false. Mr. Wyzga is accused of noting, in October 2008, that revenue increases were driven by continuing revenue increases for Cerezyme and Fabrazyme. (Compl. ¶ 268). While the Complaint makes a blanket allegation of falsity (Compl. ¶ 272), it does not specifically challenge Mr. Wyzga's figures. Finally, he is accused of stating that Fabrazyme sales were expected to increase by 14% over 2008 and that Genzyme expected Myozyme revenue to increase because it expected Lumizyme approval. (Compl. ¶ 268, 270). Again, while there is a general blanket allegation of falsity (Compl. ¶ 272, 259(a)), the Complaint does not specifically challenge the honesty of

Wyzga's expectation. Because these are forward-looking statements about Genzyme's projected revenue and were expressly identified as such,[9] the Plaintiffs must allege facts from which the Court could conclude that Mr. Wyzga had actual, contemporaneous knowledge that the predictions were false or misleading. See Exchange Act § 21E(c)(1), 15 U.S.C. § 78u-5(c)(1) (statutory safe harbor provision); *Praecis,* 2007 WL 951695 at * 10 (noting that even if "history ultimately proved [defendant's] estimates to be inaccurate," they were not actionable fraud where complaint lacked sufficient facts "to warrant a strong inference that the defendants knew the projection to be wrong at the time it was made"). There is no allegation that anyone told Mr. Wyzga, whose responsibility was finance, anything that could create an inference that he spoke with recklessness or fraudulent intent because of the alleged manufacturing problems in Allston.

With respect to the Form 10-Ks and Form 10-Qs, there is no allegation in the Complaint that gives any basis for an inference that Mr. Wyzga had any knowledge of non-financial matters that could impact the accuracy of the financial reporting and disclosures. Again, there is no allegation that is sufficient to create an inference of scienter on the part of Mr. Wyzga.

c. David Meeker

David P. Meeker was executive vice president. (Compl. ¶ 26). He "oversaw" Genzyme's Therapeutics and Biosurgery business units (*Id.*), though the Complaint never again refers to the Biosurgery business and mentions the Therapeutics unit only once, noting that Genzyme reported increased revenues from Therapeutics in the first quarter of 2008. (Compl. ¶ 234). Mr. Meeker also "was responsible for managing Genzyme's Global Manufacturing and Supply, as well as Quality." (Compl. ¶ 26). The Complaint does not explain the relationship between the

[9] Genzyme's brief (at § III.E) further details the application of the statutory safe harbor for forward-looking statements.

Therapeutics unit and the drugs at issue in the case, nor does it define the scope of Mr. Meeker's responsibilities, beyond reciting the name of his positions.

The Complaint alleges only one supposedly fraudulent statement by Mr. Meeker, namely his statement, on the first day of the class period, that "approval of Lumizyme was 'expected to come in the first quarter of [2008], allowing Genzyme to gain new commercial patients in the United States." (Compl. ¶ 217). Mr. Meeker's statement cannot be fraudulent in light of the lack of any allegations of fact that could support an inference that Mr. Meeker knew that his and Genzyme's expectation as to the timing of FDA approval of Lumizyme was inaccurate or unreasonable.

d. Alison Lawton

The Complaint alleges that Alison Lawton held various positions during the class period, including Head of Regulatory Organization, Senior Vice President of Global Product Access, Quality Systems & Regulatory Affairs, Senior Vice President of Regulatory Affairs and Corporate Quality Systems, and Senior Vice President of Global Product Access. (Compl. ¶ 28). The Complaint alleges that Ms. Lawton was "responsible for Genzyme's global regulatory activities across a broad range of products" (*Id.*). Ms. Lawton's statements relate to Genzyme's dealings with the FDA and the expected timing of Lumizyme approval. Crucially, although the Complaint alleges in several places that Ms. Lawton told investors that the FDA had, in one way or another, approved Genzyme's efforts to comply with cGMPs or had pointed toward approval for Lumizyme (e.g., Compl. ¶¶ 294, 295, 297, 304), the Complaint never alleges facts to suggest that Ms. Lawton misreported what she had heard from the FDA. The Complaint, in other words, is missing a crucial link necessary to establish Ms. Lawton's scienter. There is no fraud unless Ms. Lawton knew (or was reckless in not knowing) that what she was relating to investors about the FDA's intentions did not in fact reflect the FDA's intentions or that Ms. Lawton was actually

being told something different by the FDA than what she reported. It is implausible to infer that Ms. Lawton was accurately reporting what the FDA told her but that she should have understood that the FDA actually believed something else. The Plaintiffs' theory of the case counts on Ms. Lawton (and the others) being not just deceptive, but irrational.

e. Geoffrey McDonough

Geoffrey McDonough was a Senior Vice President. (Compl. ¶ 30). He headed the Personal Genetic Health business unit, which "encompassed the units responsible for Cerezyme, Myozyme, and Fabrazyme", the drugs on which the complaint focuses. (*Id.*). There is no explanation in the Complaint of the relationship between the Personal Genetic Health unit and the Pharmaceuticals unit under Mr. Bamforth or the Therapeutics unit under Mr. Meeker.

Dr. McDonough's statements alleged in the Complaint focus generally on expectations for FDA action on Lumizyme (e.g., Compl. ¶¶ 108, 135, 255, 270, 312, 314), on supply of Myozyme, Cerezyme, and Fabrazyme (e.g., Compl. ¶¶ 125, 238, 296), and expectations for patient demand for the drugs (e.g., Compl. ¶¶ 280, 293). These are almost entirely forward-looking statements, each time properly qualified as such. The Complaint has not alleged that Dr. McDonough knew any facts from which the Court could infer that he acted intentionally to deceive investors with his statements. *See* Exchange Act § 21E(c)(1), 15 U.S.C. § 78u-5(c)(1).

In addition to his forward-looking statements, Dr. McDonough also commented, in June 2009, about the importance Genzyme attached to the FDA's warning letter and the FDA's attitude after the reinspection of the Allston plant. (Compl. ¶¶ 147, 312). Much of what this memorandum has said for Ms. Lawton and the other Individual Defendants also applies to Dr. McDonough. Dr. McDonough related (Compl. ¶ 312) what the FDA had told Genzyme, and the Plaintiffs do not specifically allege that he was misreporting what the FDA had said at that time.

f. Mark Bamforth

Mark R. Bamforth is alleged to have made only a few statements. Mr. Bamforth was asked whether Genzyme "expect[ed] to need a subsequent inspection" (3/2/09 Trans. at 9).[10] He replied that "[w]e don't expect that" but that "[c]learly, the FDA has the liberty if they choose to do a follow up to require that. But that's not an automatic requirement. And you'll recall that we had an issue with our Lyon facility and they didn't require an inspection to lift that warning letter." (Compl. ¶ 281). The Plaintiffs imply that Mr. Bamforth "falsely assured investors" that no FDA inspection would be required in Allston (Compl. ¶ 118), but the Plaintiffs themselves allege that Mr. Bamforth noted that the FDA could conduct an inspection if it wished. Moreover, the *Wall Street Journal* article cited in the Complaint (¶ 128), which was available to investors, quotes Mr. Bamforth as saying that "the FDA indicated it planned to re-inspect the plant once Genzyme indicates it has taken all of the corrective action." David Armstrong, *FDA Warns Genzyme on Plant Conditions,* Wall St. J., Mar. 11, 2009, at B3.[11] In light of the published quote and his oral statement that the FDA could conduct an inspection if it wished, no strong inference may be drawn that that Mr. Bamforth intended to mislead investors.

Mr. Bamforth is also alleged to have "flatly (and falsely) denied that any of the deficiencies identified in the February 2009 Warning Letter would have an impact on Genzyme's ability to continue to produce … Cerezyme, Fabrazyme, and Myozyme/Lumizyme." (Compl. ¶ 119). Mr. Bamforth actually said that Genzyme did not "*anticipate* that these observations will have any impact on our supply" of the three drugs. (Compl. ¶ 282) (emphasis added), which does not support the Plaintiffs' conclusory allegation of a flat and false denial.

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[10] The transcript of the March 2 investor conference call is attached as Exhibit FF to the Declaration of Alison E.H. McLaughlin, which Genzyme has filed with its motion.

[11] A true copy of the article is attached as Exhibit 2 to the Folkman Declaration.

The Complaint also quotes the *Wall Street Journal* article, which in turns quotes Mr. Bamforth as saying that Genzyme had "addressed about 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April," that "the Boston plant continues to produce treatments," and that "the efficacy and safety of our products is unchanged." (Compl. ¶ 289). In fact, Mr. Bamforth said that Genzyme had "put together an action plan" for the FDA and was "approximately 80% complete on the program that we submitted." (3/2/09 Trans. at 6). That is, Mr. Bamforth was saying that the company had completed approximately 80% of the action plan it had submitted to the FDA, not that the problems were 80% solved or that the FDA was 80% satisfied or even that the FDA was 80% likely to accept Genzyme's efforts as sufficient. And there is no allegation that the Boston plant had ceased producing drugs at the time of the statement, or that the efficacy or safety of the drugs that Genzyme sold had changed in any way. As a result, the Complaint fails to allege sufficient facts from which the Court could infer that Mr. Bamforth acted with an intent to deceive or that he acted recklessly.

B. The Complaint Does Not State a Claim Against the Individual Defendants for Control Person Liability Pursuant to § 20(a) of the Exchange Act.

Plaintiffs assert control person claims under § 20(a) of the Exchange Act against the Individual Defendants in Count II of the Complaint, alleging Messrs. Termeer, Wyzga, McDonough, Meeker, Bamforth and Ms. Lawton are liable for securities fraud by virtue of little more than their positions in the company. The Complaint pleads Defendants' titles coupled with conclusory allegations about their "control" of Genzyme. There is nothing in the Complaint about any active role each played in statements made by the others, or in the written statements made by Genzyme. This failure requires dismissal of Count II as against the Individual Defendants because liability for securities fraud cannot be pleaded by the guessing game the Plaintiffs ask the Court to play about exactly what each Defendant supposedly did to warrant

liability under Section 20(a). *See Twombly,* 550 U.S. at 545 ("factual allegations must be enough to raise a right to relief above the speculative level").

Section 20(a) states:

> [e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

Exchange Act of 1934, § 20(a), 15 U.S.C. § 78t(a). To establish a § 20(a) claim, the Plaintiffs must plead: "(i) an underlying violation of the same chapter of the securities laws by the controlled entity . . . and (ii) control of the primary violator by the defendant." *In re Stone & Webster, Inc., Secs. Litig.,* 414 F.3d 187, 194 (1st Cir. 2005). Plaintiffs must also establish that each individual defendant was a "culpable participant" by pleading "with particularity facts giving rise to a strong inference that the controlling person knew or should have known that the primary violator, over whom that person had control, was engaging in fraudulent conduct." *Burstyn v. Worldwide Xceed Group, Inc.,* No. 01 Civ. 1125(GEL), 2002 WL 31191741, at *8 (S.D.N.Y. Sept. 30, 2002) (internal quotation omitted).[12] The purpose of § 20(a) is to prevent a person from shielding herself from liability by using another as a shell to commit acts on her behalf. *See* Lewis D. Lowenfels & Arthur R. Bromberg, *Controlling Person Liability Under Section 20(a) of the Securities Exchange Act and Section 15 of the Securities Act,* 53 Bus. Law. 1, 7-8 (1997) (discussing legislative history).

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[12] The Individual Defendants are aware that the First Circuit has reserved judgment on the Second Circuit's inclusion of culpable participation as an element of a Section 20(a) claim. *Stone & Webster*, 414 F.3d at 196 n.6. As set forth in Section B.3, *infra,* this element is clearly supported by the language of the statute and is consistent with both the goals of the PSLRA and the Supreme Court's holdings in *Twombly* and *Iqbal.* And Plaintiffs seem to acknowledge that they must plead culpable participation, see Complaint at ¶ 333, but as noted below, their rote recitation of the statutory language falls short of the mark. *Id.*

Under the most basic standard, the Complaint must allege sufficient facts to establish, at the pleading stage, a plausible claim for each Individual Defendant's liability under Section 20(a). It is not enough that Plaintiffs simply allege control by implication through defendants' titles or repeating conclusory statutory language. "[T]he PSLRA and Rule 9(b) require more …" *Swack v. Credit Suisse First Boston,* 383 F.Supp.2d 223, 246 (D. Mass. 2004). The Plaintiffs have not made allegations of control sufficient to move their claims from the realm of possibility to plausibility. *See Twombly*, 550 U.S. at 557. The control allegations here are the very definition of conclusory, and are not sufficient to justify dragging these six individuals into this case. *See Iqbal*, 129 S.Ct. at 1949. In emphasizing a plaintiff's obligation to put flesh on the bare elements of a cause of action in order to survive dismissal, the Supreme Court has recognized the potentially devastating financial consequence of defending a poorly pleaded lawsuit. *Twombly*, 550 U.S. at 559. The global problems with the Complaint's § 20(a) allegations are first addressed, and then the pleading's failure with the defendants individually.

1. The Plaintiffs' Claims Fail Because They Have Not Stated a Claim Against Genzyme, the Controlled Person.

The first element of § 20(a) liability will be satisfied only if Plaintiffs' claims against Genzyme survive. Because liability pursuant to § 20(a) is derived by virtue of a defendant's control over "others found to be primarily liable under the Exchange Act," where the underlying violations do not survive a motion to dismiss, § 20(a) claims fail as well. *Greebel*, 194 F.3d at 207. For the reasons stated in Genzyme's brief, the Plaintiffs' insufficient allegations of securities fraud under § 10(b) against the company will not support their derivative control person claims under § 20(a).

2. The Plaintiffs' Claims Fail Because They Have Not Alleged Sufficient Facts to Plausibly Assert Defendants' Control.

Fundamentally, "control" cannot be presumed when pleading a Section 20(a) claim, and thus Plaintiffs must plead the *active involvement* of each Individual Defendant in Genzyme's overall policymaking, management, decision-making, and operations. *See Aldridge*, 284 F.3d at 85. In the alternative, Plaintiffs may allege control over the specific offending statements. *See, e.g., Sloman v. Presstek, Inc.,* No. 06-cv-377-JD, 2007 WL 2740047, at *12 (D.N.H. Sept. 18, 2007); *Swack*, 383 F.Supp.2d at 246; *Rand v. M/A Com, Inc*., 824 F.Supp. 242, 262 (D. Mass. 1992). The Complaint fails on both counts. Here, allegations of defendants' control over Genzyme rest on conclusory statements repeated in a robotic refrain – that each defendant by virtue of his or her position "did influence and control, directly or indirectly, the decision-making of Genzyme," which by itself is difficult to credit given the variety and breadth of titles held by the six individuals. (Compl. at ¶¶ 359-61). Despite relying on many oral statements of particular individuals, Plaintiffs plead no facts plausibly suggesting that the other five defendants were exercising any control over those statements. Plaintiffs simply parrot the elements of §20(a) in precisely the manner condemned as insufficient by *Twombly* and *Iqbal*. *See Twombly*, 550 U.S. at 557-558; *Iqbal*, 129 S.Ct. at 1949.

A plaintiff may not rest on a title or job descriptions to establish the control element of §20(a). *Aldridge*, 284 F.3d at 85; *In re Lernout & Hauspie Secs. Litig.,* 286 B.R. 33, 39 (D. Mass. 2002); *In re Credit Suisse-AOL Secs. Litig.*, 465 F.Supp.2d 34, 61 (D. Mass. 2006); *In re Alstom SA Secs. Litig.,* 406 F.Supp.2d 433, 488 n.51 (S.D.N.Y. 2005). Where, as here, the primary violator is a corporation, asserting that the defendant possessed and exercised less than complete control over the company will not do; the Complaint must demonstrate actual control or domination. *See Aldridge*, 284 F.3d at 85; *Sheinkopf v. Stone*, 927 F.2d 1259, 1270 (1st Cir.

1991); *Rand*, 824 F.Supp. at 262); *see also In re Global Crossing, Ltd. Secs. Litig.,* No. 02 Civ. 910(GEL), 2005 WL 1875445, at *3 (S.D.N.Y. Aug. 5, 2005) (regarding parallel claims under § 15 of the Securities Act of 1933, "To be liable as a control person, the defendant must actually possess, in fact, rather than in theory, the ability to direct the actions of the controlled person" (internal quotation omitted)).

3. The Complaint Does Not Allege that the Defendants Were Culpable Participants in Genzyme's Alleged Violations.

In addition to pleading a primary violation and control, to survive a Motion to Dismiss, Plaintiffs must plead that each individual Defendant was a culpable participant with respect to that primary violation:

> In order to establish a prima facie case of controlling-person liability, a plaintiff must show a primary violation by the controlled person and control of the primary violator by the targeted defendant . . . and show that the controlling person was *"in some meaningful sense [a] culpable participant[ ] in the fraud perpetrated by [the] controlled person[ ],"*

Securities & Exch. Comm'n v. First Jersey Secs., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996) (quoting *Gordon v. Burr,* 506 F.2d 1080, 1085 (2d Cir.1974) (citation and internal quotation marks omitted)) (emphasis supplied); *see also ATSI Commc'ns, Inc. v. Shaar Fund, Ltd*., 493 F.3d 87, 108 (2d Cir. 2007); *Rochez Bros., Inc. v. Rhoades*, 527 F.2d 880, 890 (3d Cir. 1975), ("Because of this statutory scheme, we doubt that Congress would have imposed a provision like Section 20(a) and permitted liability to be found on something other than culpable participation"); *Carpenter v. Harris, Upham & Co., Inc.,* 594 F.2d 388, 394 (4th Cir. 1979); *Ballan v. Upjohn Co.*, 814 F.Supp. 1375, 1388-1389 (W.D. Mich. 1992). While some courts disagree with the Second, Third, and Fourth Circuits' holding that culpable participation is an element that must be pleaded, *see Adams v. Kinder-Morgan, Inc.,* 340 F.3d 1083, 1108-1109 (10th Cir. 2003); *Hollinger v. Titan Capital Corp*., 914 F.2d 1564, 1575 (9th Cir. 1990); *Metge v. Baehler,* 762 F.2d 621, 631 (8th Cir. 1985), the Supreme Court's reinvigoration of Fed. R. Civ.

P. 8(a) in *Twombly* and *Iqbal* demonstrate that plaintiffs must plead a "plausible" § 20(a) claim, and without an allegation of culpable participation, there is no reason to believe each defendant did not act in good faith and induced, directly or indirectly, the violation. *See Rochez*, 527 F.2d at 885 (noting that requiring defendant's culpable participation achieves Congress's intent that no one "be an insurer against the fraudulent activities of another" but instead must have been meaningfully involved in the fraud to be liable).

Requiring the careful pleading of sufficient facts to raise a strong inference of scienter as to each individual as a primary violator simply cannot be squared with permitting derivative liability—which could be even greater—as a control person simply by alleging bare facts of "control" without sufficient facts to conclude that the individual defendant was actually involved in the supposed wrongdoing. *See*, *ACA Fin. Guar. Corp. v. Advest, Inc.,* 512 F.3d 46, 56 (1st Cir. 2008) (noting that the PSLRA "meets 'twin goals: to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims'") (quoting *Tellabs,* 551 U.S. at 322). Requiring sufficient allegations of culpable participations resolves this incongruity. *Lapin v. Goldman Sachs Group, Inc.,* 506 F.Supp.2d 221, 246-47 (S.D.N.Y. 2006) (concluding that requiring element of culpable participation is most consistent with Second Circuit law and PSLRA).

Fraudulent participation, then, requires an analysis similar to that required of §10(b) claims with respect to a defendant's state of mind. *Stone & Webster*, 414 F.3d at 196 n.6 ("'Culpable participation' would seem to imply a culpable state of mind. If that is an element of a claim under § 20(a), the PSLRA's strong-inference requirement would appear to apply, as well."). *Accord In re Moody's Corp. Secs. Litig.,* 599 F.Supp.2d 493, 517 (S.D.N.Y. 2009); *Alstom,* 406 F.Supp.2d at 491.

To assert a controlling person's culpable participation, the complaint must state with particularity:

> (1) . . .defendants' awareness of facts or access to information contradicting their public statements and thus that they knew or should have known they were misrepresenting material facts related to the corporation; or (2) allege facts demonstrating that defendants failed to review or check information that they had a duty to monitor or ignored obvious signs of fraud.

Alstom, 406 F.Supp.2d at 491-92. Furthermore, claims of a defendant's digressions must amount to more than "mere deviations from standards of ordinary care," and instead must comprise "highly unreasonable or extreme misconduct." *Id.* at 491 (citations omitted). By way of example, "fraud by hindsight, positive public statements consistent with reasonably available data, failure to adequately monitor the behavior of others, and accounting violations standing alone, do not rise to the level of recklessness." *Id.* (citing *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)).

For the reasons given in Section A.3, *supra*, the Individual Defendants' participation in the activities now labeled fraudulent was neither knowingly fraudulent nor reckless. Without such culpable participation, the § 20(a) claims must be dismissed.

4. The Plaintiffs' Allegations of § 20(a) Liability Against the Individual Defendants Fall Short.

The Plaintiffs endeavor to make out the Individual Defendants' control over Genzyme, or, at the very least, over the instances of claimed misrepresentation, without providing any factual description of either their institutional responsibilities or reporting relationship to and interaction with each other. Further, any scant reference that the Complaint makes on the matter of an individual's control is premised on the Plaintiffs' "information and belief" and resorts to "and/or" pleading with such regularity that the allegations cannot be elevated above guesswork. As in *Twombly*, "[b]ecause the Plaintiffs here have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed." *Twombly,* 550 U.S. at 570.

a. Termeer.

The claims against Mr. Termeer, Genzyme's President, CEO and Chairman, rest solely upon his titles. Courts are clear that pleading titles are not sufficient to state a claim for control. *See, e.g.*, *In re Digital Island Secs. Litig.,* 223 F.Supp.2d 546, 561 n.9 (D. Del. 2002), *aff'd* 357 F.3d 322 (3d Cir. 2004) ("Notably, even a CEO is not automatically a 'controlling person' under Section 20(a)"); *Teamsters Local 617 Pension and Welfare Funds v. Apollo Group, Inc*., No. CIV 06-2674-PHX-RCB, 2010 WL 653440 (D. Ariz. Feb. 22, 2010) (court dismissed §20(a) claim against company's president where complaint was silent as to president's responsibilities).

Beyond that, there are no allegations of Mr. Termeer's active involvement, for example, in the statements made by others on conference calls, or what role he played in the preparation of Genzyme's written public disclosures. Aside from superfluous reference to Mr. Termeer's compensation, the sum and substance of the Plaintiffs' description of Mr. Termeer's control is made in two of the 362 paragraphs of the Complaint, which simply recount Mr. Termeer's titles and otherwise include conclusory allegations that he meets the statutory elements. (Compl. ¶¶ 25, 359).

Even if Mr. Termeer's control over the written disclosures of Genzyme may be presumed because of his signature on them and certification under Section 302 of the Sarbanes-Oxley Act, his fraudulent participation in those statements may not. *See In re Bayer AG Secs. Litig.*, No. 03 Civ.1546 WHP, 2004 WL 2190357, at *16 (S.D.N.Y. Sept. 30, 2004) (where complaint failed to allege that executives knew facts behind alleged fraud, control-person claims were dismissed). As set forth above, Plaintiffs have not pleaded facts sufficient to conclude that Mr. Termeer had "awareness of facts or access to information contradicting [Genzyme's] public statements" or "facts demonstrating that [he] failed to review or check information that they had a duty to monitor or ignored obvious signs of fraud." *See Alstom*, 406 F.Supp.2d at 491. As with

Plaintiffs' claims against Mr. Termeer as a primary violator, the more compelling inference from the facts alleged is that Mr. Termeer directed Genzyme to make accurate disclosures of material information when he was required to do so.

With respect to the oral statements of others, the Complaint is wholly lacking in any allegations of Mr. Termeer's active control of his colleagues' statements. There is no allegation, for example, that they were speaking from a script he prepared, or in response to his specific orders to make the statements they did. Without this connection, the Complaint falls short of establishing control under *Aldridge*, mandating not merely the power to control, but actual control over the company, or under *Swack* and other district court cases requiring that defendant exercise control over the source of the misrepresentations. *Swack*, 383 F.Supp.2d at 246; *Sloman,* 2007 WL 2740047, at *12; *In re Tyco Int'l Inc.,* No. 02-md-1335-PB, Civil No. 04-cv-1336-PB, 2007 WL 1687775, at *8 (D.N.H. Jun. 11, 2007); *Credit Suisse-AOL*, 465 F.Supp.2d at 61.

b. Wyzga

As with Mr. Termeer, allegations of Mr. Wyzga's control are confined to two short paragraphs establishing that he was Genzyme's CFO and therefore signed SEC filings, saw press releases and participated in group analyst calls. (Compl. ¶¶ 27, 361). Wholly missing are any plausible, non-conclusory allegations that Mr. Wyzga "dominated" Genzyme or exercised "virtual hegemony" over it. *See Sheinkopf*, 927 F.2d at 1270; *Rand,* 824 F.Supp. at 262. Not only do the Plaintiffs fail to connect Mr. Wyzga in theory (by virtue of his title) or in practice (by descriptive allegations) with the manufacturing process such that he plausibly knew about the problems alleged in the complaint and their implications for Genzyme's business going forward, the only inferences that may be drawn from either is that Mr. Wyzga was in charge of Genzyme's finances. This is not, however, an accounting fraud case. *Bayer*, 2004 WL 2190357, at *16 (no § 20(a) violation where plaintiffs failed to allege CFO's knowledge of supposed

problems with drugs and therefore insufficient culpable participation). As is borne out by the very few statements in the Complaint attributed directly by Mr. Wyzga, his participation consisted of signing filings and reporting almost exclusively historical financials. The conclusory allegations arising from the two projections made by Mr. Wyzga regarding sales of the biologic drugs at issue fall squarely within the safe harbor for forward-looking statements, as stated *supra,* § A.3.b. Because Mr. Wyzga's remarks are confined to Genzyme's finances, the Plaintiffs' allegations of his control over Genzyme as a whole, or of Genzyme's manufacturing processes implicated here, is even more tenuous than that for Mr. Termeer. Even if attenuated inferences were permissible, Mr. Wyzga's limited role in the Plaintiffs' tale would not be actionable because they have not met their minimum obligation to demonstrate his active knowledge of the details of Genzyme's manufacture of its biologic pharmaceuticals. The "sheer possibility" that Mr. Wyzga had sufficient knowledge of the manufacturing side of Genzyme's business to assess accuracy of the representations, based on his title and the other general control allegations, is not enough to attain the requisite plausibility. *Iqbal*, 129 S.Ct. at 1949.

c. Lawton, McDonough, Bamforth, and Meeker.

The Complaint lumps these Individual Defendants together for purposes of asserting control, perhaps hoping that where for each alone control is plainly lacking, together the allegations have more force. (Compl. ¶ 360). But § 20(a) recognizes no such theory, and such a thin basis for ascribing culpability for any alleged misstatement of Genzyme is inconsistent with the PSLRA, *Twombly* and *Iqbal*. *See, e.g.*, *In re Downey Secs. Litig.*, No. CV 08-3261-JFW (RZX), 2009 WL 2767670, at *15 (C.D. Cal. Aug. 21, 2009) ("boilerplate" allegations reciting defendants' positions, participation in setting policy, and stock ownership were "insufficient to state a claim for control person liability").

Alleging solely their titles and that they, like Mr. Termeer and Mr. Wyzga allegedly had access to written statements to the press and SEC, perhaps before issuance, perhaps after, as well as participating in group analyst calls, the Plaintiffs claim each controlled Genzyme. (Compl. ¶ 360). There are no allegations of these Defendants' roles in preparing Genzyme's financial statements, press releases, public statements or oral statements made by others. Even if their "access" to information were probative, the Complaint has not alleged that any one of them knew information contrary to what was being disclosed or had the power to "control" Genzyme. *Wells v. Monarch Capital Corp.*, No. 91-10575-MA, 1991 WL 354938, at *12 (D. Mass. Aug. 23, 1991) (the court noted of company's officers, "[t]heir titles alone, as Vice President and Corporate Controller, and as Corporate Secretary and Corporate Clerk of Monarch Capital respectively, without more specific allegation, are insufficient to state a claim under § 20(a)").

Rather than provide any guidance from which to assess any individual's control, Plaintiffs hitch their control argument to the fact that each spoke at analysts' meetings or to the press, sometimes only once.[13] This is pure boot-strapping. In essence, the Plaintiffs' position is that a person who makes a statement on behalf of a corporation is *ipso facto* in control of the corporation. Similarly, the conclusory allegation that these individuals had access to the press releases and public filings and could have prevented Genzyme from making the alleged misstatements is purely circular. The Plaintiffs are alleging that these individuals had control because they had control. There are no allegations about the roles any of these individuals played with regard to the authorization of particular allegedly fraudulent statements (other than their own statements), whether oral or in print, and no allegations about directions or instructions or even communications from one individual to another. The Plaintiffs thus hope to slip these

[13] In particular, Meeker is charged with only one statement in the 140-page complaint.

claims against the individuals through the Motion to Dismiss stage based solely on control person liability, where they have failed to plead a sufficient fraud claims against them as primary violators. But, as described above, the applicable pleadings standards have been constructed to prevent precisely such an ill-supported end run.

CONCLUSION

For the foregoing reasons, the claims against the Individual Defendants must be dismissed with prejudice for failure to state a claim on which relief can be granted.

Respectfully submitted,

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Dated: June 2, 2010

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on June 2, 2010.

/s/ Kathleen E. Cross
Kathleen E. Cross

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